

# Surgery for women with pelvic organ prolapse

<b>Submission date</b> 16/03/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/05/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/12/2019	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Pelvic organ prolapse is bulging of one or more of the pelvic organs into the vagina. Surgery to treat pelvic organ prolapse is relatively common. Around 1 in 10 women will need prolapse surgery at some point in their lives. There is not enough evidence from research to identify which operation is best. New techniques have been introduced which use mesh to reinforce the surgery, but these have not been properly tested, especially in terms of how well they improve prolapse symptoms. In particular, there is not enough information on the effectiveness and safety of the mesh used in prolapse surgery in women.

### Who can participate?

Women having a prolapse operation

### What does the study involve?

Women who are having their first repair operation are randomly allocated to undergo either a standard prolapse repair, or a standard repair with a biological graft to support the stitches, or a standard repair with a mesh to support the stitches. Women who are having their second or subsequent repair are randomly allocated to undergo either a standard prolapse repair, or a standard repair with a mesh to support the stitches, or a new mesh repair using an introducer (mesh kit). This last option is only available for women having a secondary operation for prolapse as it is thought that it is more invasive than the other options, and so should be reserved for such women because they have a higher risk of failure. Women who do not wish to be randomly allocated, but are happy for their outcomes to be monitored, are examined and complete the questionnaires in the same way as the other groups. Women have a routine gynaecological examination before surgery and they complete questionnaires both before and after their operation. Further symptom questionnaires are also filled in 6, 12 and 24 months later. The women are examined and reviewed in outpatients at 4 to 6 months after surgery.

### What are the possible benefits and risks of participating?

Not provided at time of registration

### Where is the study run from?

University of Aberdeen (UK)

When is the study starting and how long is it expected to run for?  
June 2009 to May 2014

Who is funding the study?  
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?  
Dr Cathryn Glazener  
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**Study website**  
<https://w3.abdn.ac.uk/hsru/prospect/>

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
HTA 07/60/18

## Study information

**Scientific Title**  
Clinical and cost-effectiveness of surgical options for the management of anterior and/or posterior vaginal wall prolapse: two randomised controlled trials within a comprehensive cohort study

**Acronym**

PROSPECT

**Study objectives**

Which prolapse operations are the safest and most effective and cost-effective for women with pelvic organ prolapse?

More details can be found at: <http://www.nets.nihr.ac.uk/projects/hta/076018>

Protocol can be found at: [http://www.nets.nihr.ac.uk/\\_\\_data/assets/pdf\\_file/0003/51897/PRO-07-60-18.pdf](http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0003/51897/PRO-07-60-18.pdf)

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

The study will be submitted to the North of Scotland Research Ethics Committee in April 2009 - pending

**Study design**

Multi-centre randomised controlled trial and comprehensive cohort study

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Vaginal wall prolapse

**Interventions**

All women having primary or secondary pelvic organ prolapse surgery for anterior and/or posterior vaginal wall prolapse and who consent to participate will be included in the study.

If the treating gynaecologist advises that any of the repair procedures are suitable for the patient and the woman agrees to randomisation), she will be randomised into the following arms:

For women having a primary repair:

Arm 1: Standard anterior and/or posterior repair (central plication) (reference technique)

Arm 2: Standard anterior and/or posterior repair with biological mesh inlay

Arm 3: Standard anterior and/or posterior repair with a non-absorbable or hybrid mesh inlay

In women having a secondary repair the three arms are:

Arm 1: Standard anterior and/or posterior repair (central plication) (reference technique)

Arm 2: Standard anterior and/or posterior repair with a non-absorbable or hybrid mesh inlay

Arm 3: A mesh kit (using an introducer device) with a non-absorbable or hybrid mesh

The patients who are not eligible for randomisation (if the gynaecologist advises one particular repair and/or the woman is not willing to be randomised) will be invited to consent to join the comprehensive cohort study.

All women, whether in the randomised controlled trials or the comprehensive cohort, will be followed-up in the Gynaecology Outpatients Department at around 3 to 6 months after surgery. Questionnaires will be posted to all participants at 6, 12 and 24 months after randomisation.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome measure**

1. Primary patient-reported outcome:

1.1. Symptoms of prolapse, measured as the frequency of prolapse symptoms on the Pelvic Organ Prolapse Symptom Scale (POP-SS) at two years after surgery

1.2. Quality of life (Visual Analogue Scale) outcome measured as the overall effect of prolapse symptoms on everyday life

2. Cost effectiveness: incremental cost per quality-adjusted life year (QALY) based on Euroqol EQ-5D data

All primary and secondary outcomes are measured at 6, 12 and 24 months, measured in participant-completed questionnaires.

## **Secondary outcome measures**

1. General

1.1. Immediate and late post-operative morbidity

1.2. Other adverse effects or complications including mesh erosion or removal

1.3. Operating time

1.4. Blood loss

1.5. Number of nights in hospital

1.6. Time until resumption of usual activities

1.7. Need for further surgery for prolapse or for urinary incontinence

1.8. Time to further surgery

1.9. Satisfaction with surgery

2. Prolapse outcomes

2.1. Subjective recurrence of prolapse

2.2. Subjective continuation /recurrence of prolapse symptoms

2.3. Objective residual prolapse stage (POP-Q) at original site

2.4. Development of new (de novo) prolapse at another site

2.5. Need for other conservative prolapse treatment (e.g., pelvic floor muscle training [PFMT], mechanical device)

### 3. Urinary outcomes

3.1. Urinary incontinence (persistent or de novo, and types of incontinence)

3.2. Need for alternative management for incontinence (e.g., PFMT, mechanical devices, surgery, drugs, intermittent catheterisation)

### 4. Bowel outcomes

4.1. Constipation (persistent or de novo)

4.2. Faecal incontinence (persistent or de novo)

### 5. Sexual function outcomes

5.1. Dyspareunia/ apareunia/ difficulty with intercourse

5.2. Vaginal symptoms

### 6. Quality of life outcome measures

6.1. Condition-specific quality of life measure (e.g. physical activity, social, hygiene, sexual)

6.2. General health measures

### 7. Economic outcome measures

7.1. Cost and use of NHS services

7.2. Cost to the women and their families/carers

7.3. QALYs estimated from the responses to Euroqol EQ-5D

7.4. Incremental cost per QALY (QALYs based on the SF-12® Health Survey data)

7.5. The incremental costs, QALYs and incremental cost per QALY derived by the economic model

All primary and secondary outcomes are measured at 6, 12 and 24 months, measured in participant-completed questionnaires.

### **Overall study start date**

01/06/2009

### **Completion date**

30/04/2020

## **Eligibility**

### **Key inclusion criteria**

Women (no age limits) having primary or secondary pelvic organ prolapse surgery for anterior and/or posterior vaginal wall prolapse who are willing and eligible to be randomised

### **Notes:**

1. Women who are unwilling or ineligible for randomisation will be eligible to be followed up using the same protocol as part of the comprehensive cohort

2. Women undergoing concurrent hysterectomy/cervical amputation, vault surgery or continence procedures are also eligible

### **Participant type(s)**

Patient

### **Age group**

Adult

**Sex**

Female

**Target number of participants**

4,500

**Key exclusion criteria**

1. Women undergoing prolapse surgery who are unwilling or unable to participate in the study
2. Women who are unable or unwilling to give competent informed consent, or are unable to complete study questionnaires

**Date of first enrolment**

01/06/2009

**Date of final enrolment**

31/05/2014

**Locations****Countries of recruitment**

Scotland

United Kingdom

**Study participating centre**

University of Aberdeen

Aberdeen

United Kingdom

AB25 2ZD

**Sponsor information****Organisation**

University of Aberdeen (UK)

**Sponsor details**

Research and Innovation

University Office

King's College

Aberdeen

Scotland

United Kingdom

AB24 3FX

**Sponsor type**

University/education

**Website**

<http://www.abdn.ac.uk/>

**ROR**

<https://ror.org/016476m91>

## Funder(s)

**Funder type**

Government

**Funder Name**

NIHR Health Technology Assessment Programme - HTA (UK)

## Results and Publications

**Publication and dissemination plan**

The first results should be published late 2016 with future publications due around one year after the overall end date.

**Intention to publish date**

30/04/2021

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	28/01/2017		Yes	No